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CHAPTER 5. SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness for REACH™ RCS Circular Stapler is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 878.4750

Table 5-1 General Information

Applicant:	Reach Surgical, Inc
Address:	Changping District, 29 Life Science Park Road, B-211, Beijing, China 102206
Contact Person:	Richard Fang
Telephone:	(86-10)-82894884
Email:	yrfang@gmail.com
Date of Preparation:	April 8, 2007
Device Name:	REACH™ RCS Circular Stapler
Classification Name:	Staple, Implantable
Device Class:	Class II
Product Code:	GDW
Classification Panel	General & Plastic Surgery
Type of submission	Traditional 510K

Intended use:

The REACH™ RCS Circular Stapler has applications throughout the alimentary tract for the creation of end-to-end, end-to-side and side-to-side anastomoses in both open and laparoscopic surgeries.

Indications for Use:

The REACH™ RCS Circular Stapler has applications throughout the alimentary tract for the creation of end-to-end, end-to-side and side-to-side anastomoses in both open and laparoscopic surgeries.

Device Description

The REACH™ RCS Circular Stapler is a single patient use device which places a double staggered row of titanium staples. During staple formation, the instrument knife blade resects the excess tissue, creating a circular anastomosis.

All device functions, scientific concepts, significant physical and performance characteristics (i.e. device design, materials, physical properties, etc.) are identical to the design and manufacture described in 510(k) K024275

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Substantial Equivalence Information:

Predicate Device:
Auto Suture PREMIUM PLUS CEEA Disposable Stapler by United States Surgical, 510(k) K024275.

Technological Characteristics:
The REACH™ RCS Circular Stapler's technological and safety characteristics are identical to those described in 510(k) K024275

Performance Data:
The REACH™ RCS Circular Stapler's performances is identical to those described in 510(k) K024275

Conclusion:
The data submitted in this 510(K) Premarket Notification supports the finding that this product is substantially equivalent with respect to the intended use, technology, functionality, and safety features to the legally marketed predicate device. Therefore, we believe that this device meets the requirement for a "Substantial Equivalence" decision in accordance with the 510(K) guidelines.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 8 2008

Reach Surgical, Inc.
% Mr. Richard Fang
4480 Lake Forest Drive, Suite 414
Cincinnati, Ohio 45242

Re: K071023
Trade/Device Name: REACH™ RCS Circular Stapler
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW, GAG
Dated: July 21, 2008
Received: July 22, 2008

Dear Mr. Fang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K071023

CHAPTER 4. INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: REACH™ RCS Circular Stapler

Indications for Use:

The REACH™ RCS Circular Stapler has applications throughout the alimentary tract for the creation of end-to-end, end-to-side and side-to-side anastomoses in both open and laparoscopic surgeries.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhern

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071023